



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/974,913 | 10/12/2001 | Thomas T. Hubscher | Dexall-I | 9959 |

7590

02/19/2004

Jonathan E Grant
2107 Hounds Run Place
Silver Spring, MD 20906

EXAMINER

NGUYEN, BAO THUY L

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1641

DATE MAILED: 02/19/2004

SK

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/974,913

Applicant(s)

THOMAS HUBSCHER

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-35, 38 and 68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-35, 38 and 68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 24 November 2003 has been received. Claims 36, 37, 39 and 40 have been canceled. Claim 68 has been added. Claims 27-35, 38 and 68 are pending.
2. The text of those US codes not found in this office action may be found in a previous office action.

Claim Rejections - 35 USC § 112

3. Claims 27-35, 38 and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 is vague and indefinite because the recitation of adding binding substances to a sample is a method step and since the claim is directed toward an assay device, this method step does not further limit the claimed device.

Claims 38 and 68 are vague and indefinite for the same reason above. Further, claims 38 and 68 do not further limit claim 27 since sample preparation is a process step and claim 27 is directed toward an assay device.

Claim 27 is also vague and indefinite because it is unclear what is in the reaction sites that allow it to detect the various immunoglobulins that may be present in the same. The claim recites that the reaction site is for detecting IgG, for example, where the reaction site binds a specific antibody (i.e. IgG) for which the reaction site is specific. However, the claim 27 fails to specifically state how the reaction has been modified so that it can bind the IgG.

Claim Rejections - 35 USC § 102

4. Claims 27-35, 38 and 68 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Brizgys et al (US 5,807,752).

The claims are directed toward an assay device comprising a test strip having a sample site, a colorimetric labeling site having labeled binding partner for the antibodies being detected, and at least four reaction sites, each having binding affinity for the respective antibodies.

Brizgys discloses a device comprising a porous carrier having a requisite number of receptors for analytes to be determined. See column 3, lines 20-28 and figure 1. The device also comprising a labeled binding partner for the analyte to be determined combine with a blocking agent. The label may be a gold sol, colored latex particle, etc. See column 3, lines 29-48. The test carrier also has wicking means at one end, and a waste means at the other. Capture receptors are impregnated on the device at specific locations. Brizgys teaches that both the capture and labeled receptors may be antibodies, antigens, protein A including polyclonal and monoclonal antibodies. See column 4, lines 14-16; lines 34-40 and column 5, lines 18. In one specific embodiment, a device comprising for analyte specific antibodies and one control was made to detect IgA, IgD, IgE, IgM and IgG. See columns 5 and 6.

Even though Brizgys does not disclose adding binding substances for IgG to slow the migration of the IgG relative to other immunoglobulins in the sample, this limitation is not seen to be a positive limitation of the claimed assay device, therefore, it is not given patentable weight.

Response to Arguments

5. Applicant's arguments filed 24 November 2003 have been fully considered but they are not persuasive.

Applicant argues that there is no other teaching of incorporating at the sample pad a reacting substance that will bind IgG such that it will slow down the IgG so that the activity of IgM and IgA are not eliminated or decreased. This argument has been fully considered but is not persuasive, it is noted that the feature upon which applicant relies (i.e., a sample pad comprising reactive substances that will bind IgG) is not recited in the rejected claim(s).

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

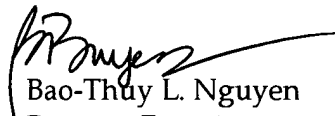
Art Unit: 1641

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641